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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,793	11/26/2003	Miguel Corona Villegas	2099.0070001/JAG/LBB	6600

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EXAMINER	
DESAI, ANAND U	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,793	CORONA VILLEGAS ET AL	
	Examiner	Art Unit	
	Anand U. Desai, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This supplemental election/restriction is in response to a response filed April 13, 2005 to the first restriction requirement mailed January 13, 2005, which had been interpreted to be an election of species rather than election of a patentably distinct invention.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 3, 31, and 32, drawn to a unique isolated nucleic acid identified by SEQ ID NO., classified in class 536, subclass 23.1.

Should Group I be elected, applicants are required to select a single nucleic acid sequence identified by SEQ ID NO. This is not a species election.

II. Claims 2, 4, 5, 6, 9, 10, drawn to a unique isolated polypeptide identified by SEQ ID NO., classified in class 530, subclass 300.

Should Group II be elected, applicants are required to select a single amino acid sequence identified by SEQ ID NO. This is not a species election.

III. Claims 7, 8, 21-28, 40, 41, 43, and 44, drawn to an conjugated composition, wherein the polypeptide in the composition is bound to a polymer substrate, classified in class 530, subclass 402.

Should Group III be elected, applicants are required to select a single amino acid sequence identified by SEQ ID NO. This is not a species election.

IV. Claims 11-14, 33, 36, 38, and 39, drawn to a method of preventing or treating envenomation from scorpion stings comprising administering to a mammal an antigenic composition, classified in class 424, subclass 185.1.

Should Group IV be elected, applicants are required to select a single amino acid sequence identified by SEQ ID NO. This is not a species election.

V. Claims 15-18, 33, 34, and 36, drawn to a method of producing and recovering antibodies against scorpion venom comprising injecting an antigenic composition, classified in class 530, subclass 403.

Should Group V be elected, applicants are required to select a single amino acid sequence identified by SEQ ID NO. This is not a species election.

VI. Claims 19, 20, 35, and 37, drawn to a composition comprising a neutralizing antibody directed to the binding fragment of the polypeptide, wherein the polypeptide is from the genus *Centruroides*, classified in class 530, subclass 387.9.

Should Group VI be elected, applicants are required to select a single amino acid sequence identified by SEQ ID NO. This is not a species election.

VII. Claims 29, and 30, drawn to a method of treating envenomation from scorpion stings comprising administering to a mammal neutralizing antibodies, classified in class 424, subclass 139.1.

Should Group VII be elected, applicants are required to select a single amino acid sequence identified by SEQ ID NO. This is not a species election.

VIII. Claims 42, 45, and 46, drawn to a diagnostic method to determine the species of scorpion, classified in class 424, subclass 9.1.

Should Group VIII be elected, applicants are required to select a single amino acid sequence identified by SEQ ID NO. This is not a species election.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II, III, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of nucleic acid, polypeptide, conjugated peptides, and antibodies have different chemical structures with different functions.

The polypeptide of group II, the conjugated composition of group III, and the polynucleotide of group I are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group I does not necessarily encode a polypeptide of groups II, or III. Furthermore, the information provided by the polynucleotide of group I can be used to make a materially different polypeptide than that of group II. In addition, while a polypeptide of group II can made by methods using some, but not all, of the polynucleotides that fall within the scope of group I, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups I, II, and III are patentably distinct.

Furthermore, searching the inventions of groups I, II, and III together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides

are not coextensive. The inventions of Groups I, II, and III have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides, which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers, which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. As such, it would be burdensome to search the inventions of groups I and II together.

The polypeptide of group II and the antibody of group VI are patentably distinct for the following reasons:

While the inventions of both group II and group VI are polypeptides, in this instance the polypeptide of group II is a single chain molecule, whereas the polypeptide of group VI encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group II and the antibody of group VI are structurally distinct molecules; any relationship between a polypeptide of group II and an antibody of group VI is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

In this case, the polypeptide of group II is a large molecule, which contains potentially hundreds of regions to which an antibody may bind, whereas the antibody of group VI is defined in terms of its binding specificity to a small structure within the amino acid sequence. Therefore the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of group II and group VI would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody that binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group VI. Furthermore, antibodies which bind to an epitope of a polypeptide of group II may be known even if a polypeptide of group II is novel. In addition, the technical literature search for the polypeptide of group II and the antibody of group VI are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The polynucleotide of group I and the antibody of group VI are patentably distinct for the following reasons. The antibody of group VI includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group VI which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino

acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group I will not encode an antibody of group VI, and the antibody of group VI cannot be encoded by a polynucleotide of group I. Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group I and group VI would impose a serious search burden since a search of the polynucleotide of group I is would not be used to determine the patentability of an antibody of group VI, and vice-versa.

3. Inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of group II can be practiced in another materially different process as disclosed in the process of preventing envenomation from scorpion stings as disclosed in Inventions IV.

4. Inventions VI and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of treating envenomation from a scorpion sting can be practiced with another materially different products as disclosed in Inventions II.

5. Inventions III and IV, V, VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for

using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in materially different processes of use, such as treating envenomation as disclosed in group IV, recovering antibodies as disclosed in group V, or a diagnostic method to determine the species of scorpion as disclosed in group VIII.

6. Inventions I and IV, V, VII, VIII are unrelated because the product of group I is not used or otherwise involved in the process of groups IV, V, VII, and VIII.

7. The inventions of Groups I, II, III, IV, V, VI, VII, and VIII have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search any combination of the inventions of Groups I, II, III, IV, V, VI, VII, or VIII together.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper. The search of Inventions is not coextensive and would therefore be burdensome.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JON WEBER
SUPERVISORY PATENT EXAMINER

June 27, 2005